that Claims 12-25 remain pending in the application. The Office raises rejections under 35 USC § 103(a).

Claims 12-25 are rejected for obviousness under 35 USC § 103(a) based on the disclosure of newly cited Johnson, et al. (US Patent No. 6,316,027) in view of Luhn (US Patent No. 6,770,368). It is the position of the Office that Johnson, et al. disclose a solid unitary fast dissolving dosage form, optionally comprising pirebedil, and a carrier including lactose. The Office acknowledges that Johnson, et al. do not specifically disclose the use of co-dried lactose and starch granules.

It is the position of the Office that Luhn discloses the use of granules consisting of lactose and starch. The Office states that the disclosed granules exhibit a friability of less than or equal to 80% and a hardness of greater than 22 N depending of the ratio of lactose and starch used and that the disclosed granules may be used in pharmaceutical preparations. In fact, the hardness quotation must be a typographical error because the Office has already acknowledged that Luhn teaches a hardness of greater than 70N (see Office Action of 1 June 2006 at page 3 noting the Luhn disclosure at column 4, line 9). It is the further position of the Office that it would have been obvious to optimize the formulation disclosed by Luhn to achieve a tablet with the desired hardness.

The Office concludes that it would have been obvious to make a tablet comprising granules consisting of co-dried starch and lactose with pirebedil because the use of granules made of co-dried lactose and starch results in good tableting capacity, good flowability, and reduced friability and that one skilled in the art would have been motivated to combine the teachings of Luhn with Johnson, et al. because the co-dried granules of lactose and starch disclosed in Luhn would improve the rapidly releasing dosage form disclosed in Johnson, et al.

Johnson, et al. disclose a pharmaceutical composition for oral administration consisting of water, sugars such as lactose, gelatin and a dopamine agonist such as piribedil. The Office acknowledges that Johnson, et al. do not disclose a composition which includes starch and certainly not a co-dried lactose/starch

composition. The compositions disclosed in Johnson, et al. are described as containing sugars as the possible carriers, and lactose is disclosed as a possible sugar; however, Johnson, et al. never disclose a composition containing lactose. In fact, every embodiment in Johnson, et al. contains mannitol as the sugar/carrier.

Luhn discloses granules consisting of lactose and starch with a tableting capacity which results in a tablet hardness greater than 70 N. Luhn also discloses (at column 4) that this tablet hardness distinguishes the disclosed compositions over prior art products. Luhn discloses that the granules possess this tableting capacity while preserving disintegrating properties, which disintegration properties Luhn characterizes as being "in the gastric medium" (col. 1, lines 30-32).

Moreover, the Applicants respectfully submit that one skilled in the art would recognize that a gastric medium is characterized by a pH less than 2.5 and a volume greater than 25 mL and that an oral medium is characterized by a pH between 5.5 and 6.5 and a volume less than 1 mL. Therefore, one skilled in the art would also recognize that the disintegration properties of a tablet in a gastric medium may not be extrapolated to an oral medium and that a coventional immediate release tablet which exhibits good disintegration properties in the gastric medium does not necessarily exhibit orodispersible properties, consisting of rapid dispersion in the mouth, before such a tablet has been swallowed.

Thus, there is nothing in the Luhn disclosure to suggest that co-dried granules consisting of lactose and starch would impart rapid release characteristics to an orodispersible pharmaceutical composition. Luhn equates the "good tableting capacity" associated with the disclosed granules with the ability of the granules to be made into a tablet with a hardness of greater than 70 N for use "in the gastric medium." The instant solid, orodispersible compositions are characterized by low friability and a lower tablet hardness which allows for rapid disintegration in the oral cavity, i.e., compositions never intended for a gastric medium. Therefore, the Applicants respectfully submit that the Luhn reference actually teaches away from the instant solid, orodispersible compositions.

Moreover, the Applicants respectfully submit that the Office has chosen to consider only limited portions of each reference for the instant combination rejection. The rapid-release properties of the composition disclosed Johnson, et al. may not find application in the gastric properties of the Luhn composition. Similarly, the "good tableting properties" associated with the lactose and starch granules disclosed in Luhn must be considered in view of the other characteristics associated with the disclosed granules (e.g., the hardness of the resulting tablet for use in a gastric environment). Therefore, when "taken as a whole", the cited references clearly do not teach or suggest the instant orodispersible compositions, and the Office has not demonstrated a motivation to combine the Johnson, et al. and Luhn references. Thus, the instant orodispersible compositions are not rendered obvious by the cited references.

Moreover, even if the teachings of Johnson, et al. and Luhn could be combined, the Applicant has already made note on the record that the mere fact that the codried lactose and starch of Luhn could be substituted for the sugar carrier of Johnson, et al. does not make out the Office obviousness allegation. The Office must establish that there was a motivation to combine the teachings of the cited art according to the compositions claimed by the applicants, and that there would be a reasonable expectation of success. (See KSR v. Teleflex, 82 USPQ2d 1385 (US 2007)) In view of the fact that the cited references teach to completely distinct functions, namely orodispersible compositions and gastric dispersible compositions, one of ordinary skill in the art would not have a reasonable expectation of success in randomly selecting elements of each technology, and have no reason to combine the teaching.

The courts have held that the mere fact that it might be **possible** to select elements of an invention by combining elements of references does not make out an obviousness rejection. See In re Bergel, 130 USPQ 206, 208 (CCPA 1961):

> The mere fact that it is **possible** to find two isolated disclosures which might be combined in such a way to produce a new compound does not necessarily

render such production obvious unless the art also contains something to suggest the desirability of the proposed combination. (Emphasis original.)

More recently, the Court of Appeals for the Federal Circuit has held that "mere identification in the prior art of each element is insufficient to defeat the patentability of the combined subject matter as a whole." In re Kahn, 78 USPQ2d 1329 (CAFC 2006)(cited with approval by the court in the KSR decision). The Office rejection would have "one skilled in the art" pick and choose among the cited teaching to:

- combine the properties of disparate compositions for oral and gastric administration;
- replace one component, i.e., lactose, by two components, i.e., co-dried lactose and starch;
- replace gelatin by co-dried starch; and
- overcome the prejudice against the hardness associated with the co-dried lactose and starch for use in an oral medium.

Surely, the Office recognizes that this represents an arbitrary and inappropriate extension of the understanding and interpretation of one skilled in the art. Reconsideration and withdrawal of the obviousness rejections is respectfully requested.

* * * * *

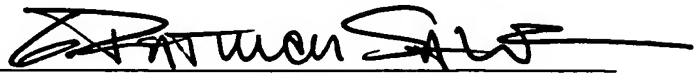
Accordingly, reconsideration of all grounds of objection and rejection, withdrawal thereof, and passage of this application to issue are all hereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is respectfully invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

By: 

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Enclosure: Check No. 76018 for $1,050.00 for three (3) month extension fee; and
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